



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/764,108      | 01/23/2004  | David Namey JR.      | 99-21 D1            | 7887             |

30031 7590 07/07/2005

MICHAEL W. HAAS, INTELLECTUAL PROPERTY COUNSEL  
RESPIRONICS, INC.  
1010 MURRY RIDGE LANE  
MURRYSVILLE, PA 15668

EXAMINER

BUTLER, PATRICK NEAL

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1732

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/764,108

Applicant(s)

NAMEY, DAVID

Examiner

Patrick Butler

Art Unit

1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-24 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 23 January 2004.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 17-20, drawn to a two-shot injection molding method of forming a mask, classified in class 264, subclass 255.
  - II. Claims 21-24, drawn to a mask, classified in class 128, subclass 206.24.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product (mask) can be made from a different process, such as adhesive bonding.
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.
6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Art Unit: 1732

7. During a telephone conversation with Mr. Michael Haas on 2/7/05 a provisional election was made with traverse to prosecute the invention of Group I, claims 17-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Specification***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) and 120 as follows:

8. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

The amendment to the specification has been considered:

#### **--CROSS-REFERENCE TO RELATED APPLICATIONS**

This application claims priority under 35 U.S.C. § 120 as a Divisional of U.S. Patent Appln. No. 09/924,849 filed August 8, 2004, which claims priority under 35 U.S.C. § 119(e) from U.S. Provisional Patent Appln. No. 60/224,912 filed August 11, 2000.--

However, the Application No. 09/924,849's filing date is noted incorrectly as August 8, 2004 rather than the actual date of August 8, 2001.

### ***Claim Rejections - 35 USC § 112***

Art Unit: 1732

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how mask seal member further comprises a second flap member in Claim 18. For purposes of examination, the claim is interpreted as including a step of attaching the second flap member.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over admitted prior art (Admission, page -1- of Spec.) in view of Namey (US Patent No. 5,902,276).

13. With respect to claim 17, prior art (Admission) discloses that two part molded masks are available, which have a mask seal and a mask body, and they are bonded together either mechanically or with an adhesive (see Specification, Paragraph 2).

14. Admission lacks or does not expressly disclose injection molding these components in a manner such that the second material is injected into the masks mold while the mask body is cooling and incompletely cured to define at least a portion of a mask seal member of the mask, wherein the mask seal member is molecularly bonded

Art Unit: 1732

to the mask body as a consequence of the second material being injected into the mask mold in this manner.

15. Namey '276 discloses a solution to the problem of the expensive and time-consuming hand assembly of a two-part unit (mask) formed of a hard plastic core (mask body) and a rubber cover (seal) (see col. 1, lines 29-40). Namey '276 teaches that a two-shot mold (mask mold) is used to facilitate manufacture by having a first injection of hard plastic (first material to form mask body) and a subsequent over molding of rubber (second material to form seal) tending to form a molecular bond to the underlying plastic (first material) to form a single unit (mask) (see col. 1, lines 56-76).

16. Namey '276 and Admission are analogous art because they both deal with the technical challenge of attaching a two-part unit of a hard core and rubber cover.

17. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a two shot mold and two shot process taught by Namey '276 to manufacture the mask body and seal in Admission in order to reduce the expense and time required to make the mask (see Namey '276 col. 1, lines 29-40), which solves the common problem of the expensive and time-consuming hand assembly of a two-part unit (mask) and in order to form a permanent and rugged seal.

18. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over admitted prior art (Admission, page -1- of Spec.) in view of Namey (US Patent No. 5,902,276) as applied to claim 17 above, and further in view of Toffolon (US Patent No. 4,971,051).

Art Unit: 1732

19. With respect to Claim 18, admitted prior art (Admission) and Namey '276 teach injecting a first material, to form a mask body, and a second material, to form a portion of a mask seal member (first flap member), into a mask mold and having the second material injected while the first material is incompletely cured to cause molecular bonding between the two materials as previously described.

20. Admission and Namey '276 lack or do not expressly disclose a second flap member that generally overlies the first flap member responsive to the mask being in an assembled configuration.

21. Toffolon does teach a mask (see Ref. 1) adapted to communicate a flow of breathing gas with an airway of a user, wherein the mask seal includes a second flap member (see Ref. 9) that generally overlies the first flap (See Ref. 11) member responsive to the mask being in an assembled configuration.

22. It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach a second flap member to the mask in the process of making a two part mask taught by Admission and Namey '276 in order to avoid skin irritations and abrasions (see Toffolon col. 1, line 42-45).

23. With respect to Claim 19, the above combination teaches that the flap ring (See Toffolon Ref. 9) (second flap member) is attached mechanically with the option of having two or one seal (interpreted to mean removable/detachable) (see col. 2, lines 16-21).

Art Unit: 1732

24. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over admitted prior art (Admission, page -1- of Spec.) in view of Namey (US Patent No. 5,902,276) as applied to claim 17 above, and further in view of Green (US Patent No. 2,664,887).

25. With respect to Claim 20, Admitted prior art and Namey '276 teach injecting a first material, to form a mask body, and a second material, to form a portion of a mask seal member (first flap member), into a mask mold and having the second material injected while the first material is incompletely cured to cause molecular bonding between the two materials as previously described.

26. Additionally, Namey '276's method of attaching two objects is to sequentially injection mold parts together. The first material is a hard plastic core (mask body), and the second material is rubber (coupling member)(see col. 1, lines 56-76).

27. Admission and Namey '276 lack or do not expressly disclose that the piece made by injecting the second material into the mask mold is a coupling member, which is molded to the mask body.

28. Green teaches a gas mask that uses a rubber (second material) coupling member (See Ref. 9) attached to the mask body (See Ref. 1)(See Col. 2, lines 12-20).

29. Namey '276 and Green are analogous art because they both deal with the technical challenge of attaching a two-part unit of a hard core and rubber cover.

30. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the rubber coupling member as taught by Green to be injection molded with the mask body using the second material as taught by Namey '276 in the two shot mold and two shot mask molding process taught by Namey '276



Art Unit: 1732

and Admission in order to have an air tight coupling (see Green col. 2, lines 27-29) and in order to reduce the expense and time required to join the mask and coupling (see Namey '276 col. 1, lines 29-40).

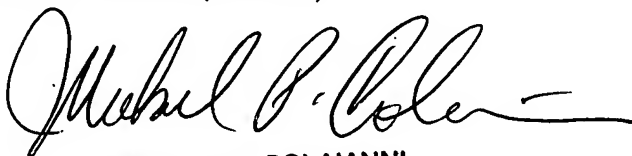
**Conclusion**

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Butler whose telephone number is 571-272-8517. The examiner can normally be reached on Monday through Friday 7:30 AM - 5:00 PM.

32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianne can be reached on 571-272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*PB*  
Patrick Butler  
Examiner  
Art Unit 1732

  
MICHAEL P. COLAIANNI  
SUPERVISORY PATENT EXAMINER